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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	10/679,081
Filing Date	10/3/2003
First Named Inventor	Hans-Michael Dosch
Art Unit	1632
Examiner Name	Lieto
Attorney Docket Number	2560.001

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
UPL		S. WINER et al, "ICA69null nonobese diabetic mice develop diabetes, but resist disease acceleration by cyclophosphamide", Journal of Immunology, 168(1):475-482 (January, 2002)	
		S. MARTIN et al, "Autoantibodies to the islet antigen ICA69 occur in IDDM and in rheumatoid arthritis", Diabetologia, 38(3):351-355 (March, 1995)	
		S. WINER et al, "ICA69null NOD congenic mice are protected from sialitis and cyclophosphamide-accelerated diabetes", Diabetes, 50(Supp 2):A503 (June, 2001) Abstract XP008028882, 2114-PO	
		K. YANAGI et al, "Anti-120-kDa alpha-fodrin immune response with Th1-cytokine profile in the NDO mouse model of Sjogren's syndrome", Eur. J. Immunol., 28(10):3336-3345 (October, 1998)	
		S. WINER et al, "Primary Sjogren's syndrome and deficiency of ICA69", The Lancet, 360(9339):1063-1069 (October, 2002)	
		R. FOX et al, "Update in Sjogren syndrome", Current Opinion in Rheumatology, 12:391-398 (2000)	
		J. JAMES et al, "Role of viruses in systemic lupus erythematosus and Sjogren syndrome", Current Opinion in Rheumatology, 13:370-376 (2001)	
		R. FOX et al, "Current issues in the diagnosis and treatment of Sjogren's syndrome", Current Opinion in Rheumatology, 11(5):364-371 (September, 1999)	
		J. HARLEY et al, "Anti-Ro (SS-A) and anti-La (SS-B) in patients with Sjogren's syndrome", Arthritis and Rheumatism, 29(2):196-206 (February, 1986)	
✓		O. BILLAUT-MULOT et al, "SS-56, a novel cellular target of autoantibody responses in Sjogren syndrome and systemic lupus erythematosus", The Journal of Clinical Investigation, 108(6):861-869 (September, 2001)	

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LDL		N. HANEJI et al, "Identification of alpha-Fodrin as a candidate autoantigen in primary Sjogren's syndrome", Science, 276:604-607 (April, 1997)	
		M. KUWANA et al, "Autoantibodies to the amino-terminal fragment of beta-Fodrin expressed in glandular epithelial cells in patients with Sjogren's syndrome", The Journal of Immunology, 167:5449-5456 (2001)	
		C. ROBINSON et al, "Transfer of human serum IgG to nonobese diabetic Igmu null mice reveals a role for autoantibodies in the loss of secretory function of exocrine tissues in Sjogren's syndrome", Proc. Natl. Acad. Sci. USA, 95:7538-7543 (June, 1998)	
		M. HUMPHREYS-BEHER et al, "Utilization of the non-obese diabetic (NOD) mouse as an animal model for the study of secondary Sjogren's syndrome". Adv. Exp. Med. Biol., 350:631-636 (1994)	
		R. HOFFMAN et al, "Sjogren's syndrome in MRL/l and MRL/n mice", Arthritis and Rheumatism, 27(2):157-165 (February, 1984)	
		N. HANEJI et al, "A new animal model for primary Sjogren's syndrome in NFS/sld mutant mice", The Journal of Immunology, 153:2769-2777 (1994)	
		J. BRAYER et al, "Sjogren's syndrome: immunological response underlying the disease", Arch. Immunol. Ther. Exp., 49:353-360 (2001)	
		C. ROBINSON et al, "A novel NOD-derived murine model of primary Sjogren's syndrome", Arthritis & Rheumatism, 41(1):150-156 (January, 1998)	
		W. KARGES et al, "Loss of self-tolerance to ICA69 in nonobese diabetic mice", Diabetes, 46:1548-1556 (October, 1997)	
		H.-MICHAEL DOSCH et al, "Persistent T cell anergy in human type 1 diabetes", The Journal of Immunology, 163:6933-6940 (1999)	

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		S. WINER et al, "ICA69 null nonobese diabetic mice develop diabetes, but resist disease acceleration by cyclophosphamide", The Journal of Immunology, 168:475-482 (2002)	
		W. KARGES et al, "Gene expression of islet cell antigen p69 in human, mouse, and rat", Diabetes, 45:513-521 (April, 1996)	
		S. WINER et al, "Type I diabetes and multiple sclerosis patients target islet plus central nervous system autoantigens; nonimmunized nonobese diabetic mice can develop autoimmune encephalitis", The Journal of Immunology, 166:2831-2841 (2001)	
		D. SERREZE et al, "B lymphocytes are essential for the initiation of T cell-mediated autoimmune diabetes: analysis of a new 'speed congenic' stock of NOD.Igmu null mice", J. Exp. Med., 184:2049-2053 (November, 1996)	
		S. WINER et al, "Peptide dose, MHC affinity, and target self-antigen expression are critical for effective immunotherapy of nonobese diabetic mouse prediabetes", The Journal of Immunology, 165:4086-4094 (2000)	
		H.-M. DOSCH et al, "Measurement of T-cell autoreactivity in autoimmune diabetes", Diabetologia, 43:386-387 (2000)	
		R. HUNGER et al, "Male gonadal environment paradoxically promotes dacryoadenitis in nonobese diabetic mice", J. Clin. Invest., 101(6):1300-1309 (March, 1998)	
		W. CHEN et al, "Evidence that a peptide spanning the B-C junction of proinsulin is an early autoantigen epitope in the pathogenesis of type 1 diabetes", The Journal of Immunology, 167:4926-4935 (2001)	
		C. LAFITTE et al, "Neurological complications of primary Sjogren's syndrome", Journal of Neurology, 248(7):577-584 (July, 2001)	

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		K. MALINOW et al, "Subacute sensory neuropathy secondary to dorsal root ganglionitis in primary Sjogren's syndrome", Ann. Neurol., 20:535-537 (1986)	
		T. CHUSED et al, "Sjogren's syndrome association with HLA-Dw3", N. Engl. J. Med., 296(16):895-897 (April, 1977)	
		H. FOSTER et al, "Linkage studies of HLA and primary Sjogren's syndrome in multicase families", Arthritis and Rheumatism, 36(4):473-484 (April, 1993)	
		E. GOILLOT et al, "Sialadenitis in nonobese diabetic mice: transfer into syngeneic healthy neonates by splenic T lymphocytes", Clin. Immunol. Immunopathol., 59:462-473 (1991)	
		K. YANAGI et al, "Anti-120-kDa alpha-fodrin immune response with Th1-cytokine profile in the NDO mouse model of Sjogren's syndrome", Eur. J. Immunol., 28:3336-3345 (1998)	
		R. MASAGO et al, "Elevated Proapoptotic Bax and Caspase 3 activation in the NOD.scid model of Sjogren's syndrome", Arthritis & Rheumatism, 44(3):693-702 (March, 2001)	
		C. ROBINSON et al, "Genetically programmed development of salivary gland abnormalities in the NOD (nonobese diabetic)-scid mouse in the absence of detectable lymphocytic infiltration: a potential trigger for sialoadentitis of NOD mice", Clin. Immunol. Immunopathol., 79(1):50-59 (April, 1996)	
✓		J. GROOM et al, "Association of BAFF/BLyS overexpression and altered B cell differentiation with Sjogren's syndrome", The Journal of Clinical Investigation, 109(1):59-68 (January, 2002)	

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